MAY 21 2003

510(K) SUMMARY

MYTHOS 500™ DIODE LASER SYSTEM

510(k) Number K 030805

Applicant's Name: Msq(M^2) Ltd.
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Caesarea Industrial Park 38900 Israel
Tel: 04-6275357
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e-mail: zivk@Msq.co.il

Contact Person: Arava Hacohen
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
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Date Prepared: February 2003

Trade Name: MYTHOS 500™ Hair Removal Diode Laser

Classification Name: Laser Instrument, Surgical, powered

Classification: FDA has classified a laser device as a class II device (product code GEX) and it is reviewed by the General & Plastic Surgery Panel.

Predicate Device: Msq(M^2) Ltd. believes that the MYTHOS 500™ Diode Laser System is substantially equivalent to the LightSheer™ (Coherent Star) cleared under K001746 and K003614 in terms of intended use and indications for use, performance, technological characteristics and user interface.

Performance Standards: The MYTHOS 500™ Hair Removal Diode Laser complies with U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.

In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the voluntary standards, IEC 60601-1, IEC 60601-1-2, IEC-60825-1 and IEC 601-2-22, as described in **Section 5**.

Intended Use / Indication for Use: The MYTHOS 500™ Hair Removal Diode Laser is intended for hair removal and permanent hair reduction. The MYTHOS 500™ System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

Device Description: The MYTHOS 500™ system delivers pulsed infrared laser light with a 810nm±10% wavelength and a selectable fluence of 5-60J/cm^2. The system enables two pulse modes: Long pulse and Pulse.
The pulsed energy is delivered through a 10x12mm handpiece tip.
The complete system consists of console and a handpiece connected to the system by an umbilical cord. The handpiece is pressed against the patient's skin and a pulse of laser is delivered. To initiate energy output the system requires simultaneous activation of the handpiece trigger and the footswitch. The handpiece tip is cooled to provide continuous skin cooling. Laser parameters and other system features are controlled from the Operating Buttons and LCD screen on top of the console, which provide interface with the system computer.

Substantial Equivalence: There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The MYTHOS 500™ intended use and indications for use were previously cleared by FDA for the predicate device (LightSheer).
- The technical characteristics of the MYTHOS 500™ are similar to those of the LightSheer™.
- Laser output values of the MYTHOS 500™ are well within previous cleared values of the LightSheer™.
- Safety and performance testing.

Therefore, we believe that the MYTHOS 500™ Hair Removal Diode Laser is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Msq (M^2) Ltd.
c/o Mr. Arava Hacohen
Push-med Ltd.
117 Ahuzah St.
Ra'ananna 43373, Israel

Re: K030805
Trade/Device Name: MYTHOS 500™ Hair Removal Diode laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 13, 2003
Received: March 13, 2003

Dear Mr. Hacohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K030805

Device Name: MYTHOS 500™ Hair Removal Diode Laser System

Indications for Use:

The MYTHOS 500™ Hair Removal Diode Laser is intended for hair removal and permanent hair reduction. The MYTHOS 500™ System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K030805

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030805